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# COVID-19 Vaccination Education

## Moderna

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Thank you for your commitment to getting vaccinated. Included in this packet is the information that you need to know:

- Emergency Use Authorization of Moderna COVID-19 Vaccine.
- Next steps after receiving the COVID-19 Vaccine including symptom monitoring.
- Centers for Disease Control and Prevention Vaccine Safety (V-Safe) symptom reporting.

You must come back for your second vaccine dose. Your second dose appointment was scheduled when you made your appointment for today. If you need to change your second dose appointment, please call: 612-467-1100 or 1-866-414-5058. Please make all possible efforts to keep your already scheduled second dose appointment. Bring this packet with you to your second dose appointment.

## A Guide to Available Services for Enrolled Veterans

Minneapolis VA Health Care System (MVAHCS) is a teaching hospital providing a full range of patient care services with state-of-the-art technology, education, and research. Comprehensive health care is provided through primary care, tertiary care and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, geriatrics, extended care and 13 Community Based Outpatient Clinics (CBOC) across the region.



- ✓ VHA is the largest integrated health care system in the United States, providing care at 1,227 health care facilities, including 168 VA Medical Centers and 1,047 outpatient sites of care of varying complexity.
- ✓ As of 2016, VA Consolidated Mail Outpatient Pharmacy received the highest customer satisfaction among the nation's public and private mail-order pharmacies, according to a J.D. Power study. Nearly 5 million Veterans receive their prescriptions through VHA pharmacies.
- ✓ VA is the national leader in telehealth services. VA telehealth services are critical to expanding access to VA care in more than 45 clinical areas.

### Services Available at the Minneapolis VA Health Care System

Audiology & ENT	Neurology & Neurosurgery	Primary Care
Cardiology	Nutrition	Prosthetics
Dental	Oncology/Cancer Care	Rehabilitation
Dermatology	Ophthalmology	Respiratory Services
General Surgery	Optometry	Telehealth Services
Home Care Services	Orthopedics	Thoracic Surgery
Hospice/Palliative Care	Orthotics	Urology
Mental Health Services	Pharmacy	Vascular Surgery
MOVE! Weight Management	Podiatry & Wound	Women's Health
Whole Health & Integrative Health Services		

#### IMPORTANT NUMBERS

##### Minneapolis VA Health Care System:

(612) 725-2000 • Toll Free: (866) 414-5058

##### Primary Care Call Center:

(612) 467-1100 • Toll Free: 1 (866) 414-5058

##### Enrollment:

1 (877) 222-VETS (8387)

##### Benefits:

1-800-827-1000



For more information, please visit:

[www.minneapolis.va.gov](http://www.minneapolis.va.gov)

[www.va.gov](http://www.va.gov)

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS  
EMERGENCY USE AUTHORIZATION (EUA) OF  
THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019  
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER**

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

**WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

**WHAT IS COVID-19?**

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

**WHAT IS THE MODERNA COVID-19 VACCINE?**

The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?**

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

## **WHO SHOULD GET THE MODERNA COVID-19 VACCINE?**

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

## **WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?**

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

## **WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?**

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

## **HOW IS THE MODERNA COVID-19 VACCINE GIVEN?**

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

## **HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?**

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

## **WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?**

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

## WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

## WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

**WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?**

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?**

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

**CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

**WHAT IF I AM PREGNANT OR BREASTFEEDING?**

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

**WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?**

No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.


**KEEP YOUR VACCINATION CARD**

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

**ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
<a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a> 	1-866-MODERNA (1-866-663-3762)

**HOW CAN I LEARN MORE?**

- Ask the vaccination provider
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- Contact your state or local public health department

## **WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

## **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

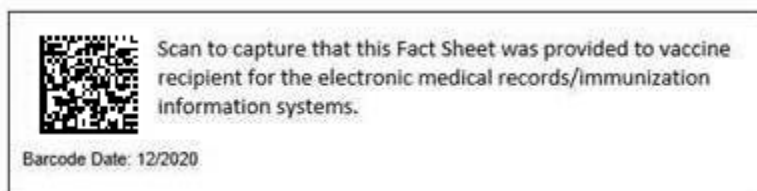
The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)

Revised: 12/2020



Revised: December 2020



## NEXT STEPS after receiving the COVID-19 Vaccine

### VA Side Effects and Adverse Events Reporting Fact Sheet

Whether you are an employee or a Veteran receiving the COVID-19 vaccine, you have taken an important step towards protecting yourself, your family and friends, and your communities from COVID-19.

#### Now that you have received the vaccine, what can you expect?

Vaccines protect us by stimulating the body's natural immune system to produce antibodies to fight a virus. This is called an immune response. Vaccines are a way to trigger the immune response to allow the body to protect against becoming infected and getting sick from illnesses like COVID-19.

Many people who receive the COVID-19 vaccine who experience a reaction have mild symptoms. These may include your arm being sore, red, or warm to the touch. These symptoms usually go away on their own within a few days to a week. Some people report getting a headache, fatigue, fever, or muscle aches when getting a vaccine. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.

It is important to know what side effects to expect and which ones should be reported to your healthcare team. Contact your health care provider if your symptoms make you unable to work, do daily activities, or if you feel that you need urgent care for any of these symptoms. This reporting is part of the Emergency Use Authorization (EUA) safety monitoring process required by the U. S. Food and Drug Administration (FDA). You can play an important role in this process.

The following potential side effects may occur with COVID-19 vaccines:

#### Local symptoms at the injection site include:

Pain - Discomfort  
Redness  
Swelling  
Itching

#### General symptoms (not at the injection site) include:

Chills	Muscle or Body Aches (myalgia)	Diarrhea
Fever	Fatigue or Tiredness	Rash - Not at Injection Site
Headache	Nausea	Allergic Reaction
Joint Pains (arthralgia)	Vomiting	Swollen Glands

If you experience a reaction to the vaccine, please use the table on the back of the sheet to record your symptoms and the day that you experienced them.

If you experience these symptoms **and they have an impact on your daily routine**, please contact your provider and record your information in the table on the back of this sheet.

- If you are an **employee** and experience symptoms to the COVID-19 vaccine that impact daily activities, please contact your local Employee Occupational Health department at \_\_\_\_\_.
- If you are a **Veteran** and experience symptoms to the COVID-19 vaccine that impact daily activities, please contact your healthcare team at [612-467-1100](tel:612-467-1100).

You will be returning for a 2nd dose on: \_\_\_\_\_. Please bring this sheet and your Vaccination Record card when you return for your next appointment.

It is important for you to return for the 2nd dose to maximize immunity from the vaccine to protect yourself, your family and friends, and your community.



# COVID-19 Vaccine Monitoring Record

December 2020

			Dose 2	
Day	Have you had any injection site symptoms? Check if yes (write which one)	Have you had any general symptoms? Check if yes (write which one)	Have you had any injection site symptoms? Check if yes (write which one)	Have you had any general symptoms? Check if yes (write which one)
1 (day of vaccination)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Week				
2 (up to 14 days after vaccination)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 (up to 21 days)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 (up to 28 days)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 (up to 35 days)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 (up to 42 days)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other important events

**Please contact your provider/clinic immediately if any of the following occur after you receive the vaccine:**

- You are admitted to the hospital for any reason
- You receive a positive test for COVID-19
- If female, you become pregnant

**Notes (any additional info):** (any info needed to collect - temperature/date if fever; medication taken; reported to doctor/clinic/ER; COVID-19 test)



**Get vaccinated.  
Get your smartphone.  
Get started with v-safe.**

## ***What is v-safe?***

**V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second

COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

## ***How can I participate?***

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

## ***How long do v-safe check-ins last?***

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

## ***Is my health information safe?***

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.\*

\*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



after vaccination

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



**Sign up with your  
smartphone's browser at  
[vsafe.cdc.gov](https://vsafe.cdc.gov)**

**OR**

**Aim your smartphone's  
camera at this code**

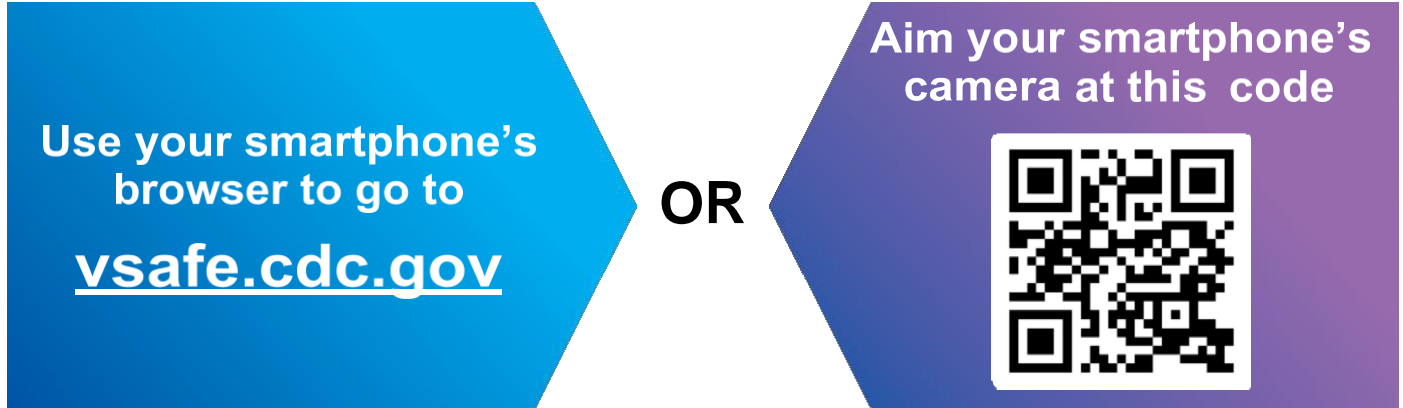


# How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

## Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **v-safe** will start your initial health check-in immediately after you register—just follow the instructions.

You will receive a reminder text message from **v-safe** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

## Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

## Troubleshooting

### How can I come back and finish a check-in later if I'm interrupted?

- ▣ Click the link in the text message reminder to restart and complete your check-in.

### How do I update my vaccine information after my second COVID-19 vaccine dose?

- ▣ **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

### Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)

